

Message Text

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ORIGIN HEW-06

INFO OCT-01 ISO-00 AF-06 ARA-10 EA-09 EUR-12 NEA-10 OES-05

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DRAFTED BY: DHEW/FDA:JRWEINROTH, MD.D.: AMS

APPROVED BY: OES/APT/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

ARA/NSC-IG:RJBLOOMFIELD (INFO)

AF/S:RJDOLS (INFO)

EUR/NSC-IG:JROUSE(INFO)

NEA/IRN:CWNAAS (INFO)

EA/ANP:MMICHAUD (INFO)

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P 282209Z OCT 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY SAN JOSE PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY TEHRAN PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY PRETORIA PRIORITY

AMEMBASSY LONDON PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, AS, BE, CS, EC, ES, GW, IR, IT, NU, SF

SUBJ: FDA ADVISORY - MOSLABELLED CONTROL SERUM

1. FDA ADVISES THAT THE:

PRODUCT: CHEMISTRY CONTROL SERUM II. BLUE AND WHITE CARDBOARD

CARTON CONTAINING 6 AMBER GLASS VIALS LABELLED IN PART; "5 ML,

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DRIED Q-PAK RECONSTITUTE WITH 5.0 ML DISTILLED WATER, AGITATE

GENTLY. SEE PACKAGE INSERT FOR CONSTITUENT LEVELS AND DIRECTIONS FOR USE. FOR IN-VITRO DIAGNOSTIC USE. STORE BETWEEN 2 DEGREES AND 8 DEGREES C BEFORE AND AFTER RECONSTITUTION. LOT NO. EXPIRATION DATE ... HYLAND DIVISION TRAVENOL LABORATORIES, INC. COSTA MESA, CALIFORNIA 92626, USA". THE CARTON CONTAINS PACKAGE INSERT TITLED Q-PAK - CHEMISTRY CONTROL SERUM II ANALYSIS, LOT NO. 0368G008A3 ... REVISED FEBRUARY 1975. ALSO ENCLOSED IN THE CARTON IS A SPECIAL NOTICE STATING THAT THE VALUE GIVEN FOR IRON-BINDING CAPACITY (TIBC) IS ERRONEOUS,

LOT NUMBER: 0368G008A3
MANUFACTURER:
HYLAND DIVISION OF TRAVENOL LABS.
RT. 120 AT WILSON ROAD
ROUND LAKE, ILLINOIS 60073
DISTRIBUTION: 6,999 UNITS DISTRIBUTED BETWEEN 4/10/75 AND 9/12/75.

REASON FOR ADVISORY: HYLAND CONTRAOL SERUM II IS USED BY LABORATORIES

AS A GUIDE FOR EVALUATING THE ACCURACY AND PRECISION OF LABORATORY TEST PROCEDURES. CONSTITUENT VALUES FOR FIVE TESTS AND THE METHODOLOGY FOR TOTAL BILIRUBIN ARE LISTED INCORRECTLY ON THE PACKAGE INSERT. THE ERRONEOUS CONSTITUENT VALUES LISTED IN THE LABELLING MAY RESULT IN INCORRECT DIAGNOSTIC READINGS OF PATIENTS SERUM WHICH MAY LEAD TO IMPROPER TREATMENT. ON SEPTEMBER 4, 1975 THE FIRM SENT ADVISORY LETTERS TO LABORATORY DIRECTORS AND DEALERS ADVISING THEM THAT APPROPRIATE ADJUSTMENTS MUST BE MADE WHEN USING THIS LOT OF CONTROL SERUM. THESE CORRECTIONS APPLY ONLY TO LOT NO. 0368G00883 OF CONTROL SERUM II.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED THE SEPTEMBER 4, 1975 ADVISORY LETTER FROM HYLAND LABORATORIES. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO THE FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

TRAVENOL LABORATORY PTY AUSTRALIA 01
P.O. BOX 88 TOONGABBIE
NSW 2146 AUSTRALIA
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PH ON ARR 636-2000

TRAVENOL BELG - FOR FRANCE 14
C/O AIR EXPRESS INTNL
BRUSSELS NATL AIRPORT
BRUSSELS, BELGIUM

TRAVENOL LABS BELGIUM 02

C/O AIR EXPRESS INTL
BRUSSELS NATL AIRPORT
BRUSSELS, BELGIUM

INDUSTRICAS QUIMICAS S.A.
AVENIDA 14
CALLE CENTRAL PRIMERA
SAN JOSE, COSTA RICA

IMPORTADOR SEBILLER CIA
OFICINA NO. 51
APARTADO 2716
QUITO, ECUADOR

DROGERIA PRO-MEDICI, SA
APARTADO POSTAL 1503
SAN SALVADOR
EL SALVADOR

INST. HONDURENO DE SEGURO
SOCIAL
SAN SALVADOR
EL SALVADOR

TRAVENOL INTL. GMBR GERMANY 08
C/O ATLANTIC INTL DMBH
8 MUNICH RIEM AIRPORT
GERMANY

SA-ID TABIBI AND COMPANY
69 SHAB REZA AVE.
IRAN

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TRAVENOL LABS ITALY
AERO STAZIONE MERCI
L DA VINCI AIRPORT
FIUMICINO ROME ITALY

COMMERCIAL R ZAMORANA S.A.
KM 71-2 CARRETERA SUR
MANAGUS D.N.
NICARAGUA, C.A.

KEA GRAMS LTD
P.O. BOX 6888
JOHANNESBURG
SAOUTH AFRICA

TRAVENOL LABS ENGLAND
CAXTON WAY LONDON R
THETFORD NORFOLK, ENGLAND. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD & DRUG REGULATIONS, RECALLS, CHEMICALS
Control Number: n/a
Copy: SINGLE
Draft Date: 28 OCT 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE255445
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, MD.D.: AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750374-0153
From: STATE
Handling Restrictions: n/a
Image Path:
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Legacy Key: link1975/newtext/t19751016/aaaaaonm.tel
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Office: ORIGIN HEW
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Original Previous Classification: n/a
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Review Comment: n/a
Review Content Flags:
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Review Event:
Review Exemptions: n/a
Review History: RELEASED <12 SEP 2003 by MaustMC>; APPROVED <10 FEB 2004 by buchant0>
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Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

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Review Transfer Date:
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Status: NATIVE
Subject: FDA ADVISORY - MOSLABELLED CONTROL SERUN
TAGS: OGEN, ETRD, TBIO, AS, BE, CS, EC, ES, GE, IR, IT, NU, SF
To: CANBERRA MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006